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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : CHEUNG, Nai-Kong V.

U.S. Serial No.: 09/982,645, claiming benefit of U.S. Serial No. 60/241,344, filed on October 18, 2000

Filing Date : October 18, 2001 Group Art Unit: 1645

For : USES OF MONOCLONAL ANTIBODY 8H9

Law Offices of Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357

May 17, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant had submitted an Information Disclosure Statement containing 175 references on January 23, 2002 in connection with the above-identified application.

In accordance with his duty of disclosure under 37 C.F.R. § 1.56, Applicant would like to direct the Examiner's attention to the following references in this Supplemental Information Disclosure Statement which are listed on Form PTO-1449 (**Exhibit A**) and are attached hereto as Exhibits 1 through 74, respectively:

1. 02 April 2002 International Search Report from Patent Cooperation Treaty for International Patent Application

USES OF MONOCLONAL ANTIBODY 8H9 for SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, et al. International application No. PCT/US01/32565, International Filing Date 18 October 2001, claiming benefit of U.S. Serial No. 60/241,344, filed 18 October 2000, and U.S. Serial No. 60/330,396, filed 17 October 2001. Three full-text citations in the International Search Report are attached as **Exhibits 2, 3** and **4** in this Supplemental Information Disclosure Statement. One full-text citation in the International Search Report was included as Exhibit 131 of the January 23, 2002 Information Disclosure Statement. (**Exhibit 1**)

2. JUHL, et al., Additive Cytotoxicity of Different Monoclonal Antibody-Cobra Venom Factor Conjugates for Human Neuroblastoma Cells, Immunobiology, November 1997, vol. 197, pp.444-459 (**Exhibit 2**)

3. MODAK, et al., Radioimmunotargeting to Human Rhabdomyosarcoma (RMS) using Monoclonal Antibody (MOAB) 8H9, Proceedings of the American Association for Cancer Research Annual Meeting, March 2000 vol. 41 PP.724, Abstract 4600. (**Exhibit 3**)

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6. Bigner, D. D., Brown, M. T., Friedman, A. H., Coleman, R. E., Akabani, G., Friedman, H. S., Thorstad, W. L., Mclendon, R. E., Bigner, S. H., Zhao, X. G. Iodine-131-labeled antitenascin monoclonal antibody 81C6 treatment of patients with recurrent malignant gliomas:phase I trial results. Journal Clincal Oncology, *16*:2202-2212, 1998. (**Exhibit 6**)

7. Bruland, O., Fodstad, O., Funderud, S., Pihl, A. New monoclonal antibodies specific for human sarcomas. Int J Cancer, *15*:27-31, 1986. (**Exhibit 7**)

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10. Mariani, G., Lasku, A., Pau, A., Villa, G., Motta, C., Calcagno, G., Taddei, G. Z., Castellani, P., Syrigos, K., Dorcaratto, A., et al. A pilot pharmacokinetic and immunoscintigraphic study with the technetium-99m-labeled monoclonal antibody BC-1 directed against oncofetal fibronectin in patients with brain tumors. Cancer Supplement, *80*:2484-2489, 1997.(**Exhibit 10**)

11. DiMaggio JJ, Scheinberg DA, Houghton AN: Monoclonal antibody therapy of cancer. In: Pinedo HM, Chabner BA, Longo DL, (eds.): Cancer Chemotherapy and Biological Response Modifiers, Annual 11, Elsevier Science Publishers B.V., (Biomedical Division), 1990, pp 177-203 (**Exhibit 11**)

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19. Larson SM, Sgouros G, Cheung NK: Antibodies in cancer therapy: Radioisotope conjugates. In: DeVita VT, Hellman S, Rosenberg SA, (eds.): Biologic Therapy of Cancer, 2nd ed. Philadelphia, J.B. Lippincott Co., 1995, pp 534-552 (**Exhibit 19**)

20. Reisfeld RA, Mueller BM, Handgretinger R: Potential of genetically engineered anti-ganglioside GD2 antibodies for cancer immunotherapy. In: Progress in Brain Search (Svennerhol,L, Asbury,AK, Reisfeld,RA, Sandhoff,K, Suzuki,K, Tettamani,G, Toffano,G, vol. 101. Cambridge, UK, Elsevier Trends Journals, 1994, pp 201-212 (**Exhibit 20**)

21. Cheung NKV, Walter EI, Smith-Mensah WH, et al: Decay-accelerating factor protects human tumor cells from complement-mediated cytotoxicity in vitro. J Clin Invest 81:1122-1128, 1988 (**Exhibit 21**)

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27. Yu AL, Gillies SD, Reisfeld RA: Phase I clinical trial of ch14.18 in patients with refractory neuroblastoma. Proc Am Soc Clin Oncol 10:318, 1991, Abstract 1118 (**Exhibit 27**)

28. Cheung NK: Biological and Molecular Approaches to Diagnosis and Treatment. Immunotherapy. In: Pizzo PA, Poplack DG, (eds.): Principles and Practice of Pediatric Oncology, 2nd ed. Philadelphia, J.B.Lippincott Company, 1992, pp 357-370 (**Exhibit 28**)

29. Cheung NKV, Kushner BH, Yeh SJ, Larson SM: 3F8 monoclonal antibody treatment of patients with stage IV neuroblastoma: A phase II Study. Int J Oncol 12:1299-1306, 1998 (**Exhibit 29**)

30. Cheung NK, Yeh SD, Kushner BH, et al: Phase I study of radioimmunotherapy of neuroblastoma using iodine 131 labeled 3F8. In: Prog. Clin. Biol. Res: Advances in Neuroblastoma Research 4. New York, Wiley Liss, 1994, pp 329 (**Exhibit 30**)

31. Kramer K, Cheung NKV, DiResta G, et al: Pharmacokinetics and acute toxicology of intraventricular ^{131}I-monoclonal antibody targeting disialoganglioside in non-human primates. J Neuro Oncol 1996 (**Exhibit 31**)

32. Saleh MN, Wheeler RH, Khazaeli MB, et al: Phase I trial of chimeric anti-GD2 monoclonal antibody C14.18 in patients with metastatic melanoma. Hum. Antibod. Hybridomas, 1992, vol 3, January (**Exhibit 32**)

33. Cheung IY, Cheung NKV, Kushner BH: Induction of Ab3' following anti-GD2 monoclonal antibody 3F8 therapy predicts survival among patients (pts) with advanced neuroblastoma. Proc Am Assoc Cancer Res 40:574, 1999, Abstract 3787 (**Exhibit 33**)

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51. de Wynter EA, Coutinho LH, Pei X, et al. Comparison of purity and enrichment of CD34+ cells from bone marrow, umbilical cord and peripheral blood (primed for apheresis) using five separation systems. Stem Cells. 1995; 13:524-32. (**Exhibit 51**)

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54. Gerald, W.L., et al. Intra-abdominal desmoplastic small round-cell tumors: report of 19 cases of distinctive type of high-grade polyphenotypic malignancy affecting young individuals Am. J. Surg. Pathol. 15(6): 499-513, (1991) (**Exhibit 54**)

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57. George, A.J.T., Spooner, R.A. and Epenetos, A.A. (1994) Applications of Monoclonal Antibodies in Clinical Oncology. Immunology Today 15, 559-561. (**Exhibit 57**)

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62. Rosenberg, S. A. Cell transfer therapy: clinical applications. *In:* V. T. J. DeVita, S. Hellman, and S. A. Rosenberg (eds.), Biologic therapy of cancer, second edition, pp. 487-506. Philadelphia: J.B.Lippincott Company, 1995. (**Exhibit 62**)

63. Yang, A.-G. and Chen, S.-Y. A new class of antigen-specific killer cells. Nat Biotechnol, *15:* 46-51, 1997. (**Exhibit 63**)

64. Culver, K. W., Ram, Z., Wallbridge, S., Ishii, H., Oldfield, E. H., and Blaese, R. M. In vivo gene transfer with retroviral vector-producer cells for treatment of experimental brain tumors. Science, *256:* 1550, 1992. (**Exhibit 64**)

65. Jensen, M., Tan, G., Forman, S., Wu, A. M., and Raubitschek, A. CD20 is a molecular target for scFvFc: receptor redirected T cells: implications for cellular

immunotherapy of CD20+ malignancy. Biol Blood Marrow Transplant, *4:* 75-83, 1998. (**Exhibit 65**)

66. Fitzer-Attas, C.J. and Eshhar, Z. Tyrosine kinase chimeras for antigen-selective T-body therapy. Adv Drug Deliv Rev, *31:* 171-182, 1998. (**Exhibit 66**)

67. Valitutti, S. and Lanzavecchia, A. Serial triggering of TCRs: a basis for the sensitivity and specificity of antigen recognition. Immunology Today, *18:* 299-304, 1997. (**Exhibit 67**)

68. Ruymann FB and Grovas AC. Progress in the diagnosis and treatment of rhabdomyosarcoma and related soft tissue sarcomas. Cancer Invest 18:223-241, 2000 (**Exhibit 68**)

69. Cheung NK, Neely JE, Landmeier B, Nelson D and Miraldi F. Targeting of ganglioside GD2 monoclonal antibody to neuroblastoma J Nuc Med 28:1577-83, 1987 (**Exhibit 69**)

70. Thomson B, Hawkins D, Felgenhauer J, and Radich J. RT-PCR evaluation of peripheral blood, bone marrow and peripheral blood stem cells in children and adolescents undergoing VACIME chemotherapy for Ewing's sarcoma and alveolar rhabdomyosarcoma. Bone Marrow Transplant 24:527-33, 1999 (**Exhibit 70**)

71. Athale UH, Shurtleff SA, Jenkins JJ, Poquette CA, Tan M, Downing JR and Pappo AS. Use of Reverse

Transcriptase Polymerase Chain Reaction for Diagnosis and Staging of Alveolar Rhabdomyosarcoma, Ewing Sarcoma Family of Tumors, and Desmoplastic Small Round Cell Tumor. Am J Pediatr Hematol Oncol 23(2):99-104, 2001 (**Exhibit 71**)

72. Mackall C, Berzofsky J and Helman LJ. Targeting tumor specific translocations in sarcomas in pediatric patients for immunotherapy. Clin Orthop. 373:25-31, 2000 (**Exhibit 72**)

73. Gruchala A, Niezabitowski A, Wasilewska A, Sikora K, Rys J, Szklarski W, Jaszcz A, Lackowska B and Herman K. Rhabdomyosarcoma. Morphologic, immunohistochemical, and DNA study. Gen Diagn Pathol 1142:175-84, 1997 (**Exhibit 73**)

74. Kalebic T, Tsokos M, Helman LJ. In vivo treatment with antibody against IGF-1 receptor suppresses growth of human rhabdomyosarcoma and down-regulates $p34^{cdc2}$. Cancer Res 54:5531-4, 1994 (**Exhibit 74**)

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement (§1.97(c)).

However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Applicant's Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai-Kit Chan

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I hereby certify that this paper is being deposited this date with the U.S. Postal Service with sufficient postage for first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Albert Wai-Kit Chan 5/17/02
Albert Wai-Kit Chan Date
Reg. No. 36,479

Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 638-A	Serial No. 09/982,645
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Applicants CHEUNG, Nai-Kong V.	
	Filing Date 10/18/01	Group 1645

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	1	International Search Report 2 April 2002 International Search Report from Patent Cooperation Treaty for International Patent Application USES OF MONOCLONAL ANTIBODY 8H9 for SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, et al. International application No. PCT/US01/32565, International Filing Date 18 October 2001, claiming benefit of U.S. Serial No. 60/241,344, filed 18 October 2000, and U.S. Serial No. 60/330,396, filed 17 October 2001. **(Exhibit 1)**
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	19	Larson S.M. et al.
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